IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: COLOPLAST CORP. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: *All Coloplast Wave 5, 6, and 7 cases*	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE OR LIMIT CERTAIN OPINIONS AND TESTIMONY OF BRUCE ROSENZWEIG, M.D.

The Plaintiffs respectfully request that this Court deny Defendant Coloplast Corp.'s ("Coloplast's") Motion to Exclude or Limit Certain Opinions and Testimony of Bruce Rosenzweig, M.D., for the reasons stated below.

INTRODUCTION

Dr. Rosenzweig's opinions have been vetted as much as any other expert in the various MDLs. This Court has consistently found him well qualified to testify on a wide variety of topics. For instance, in one order denying Ethicon, Inc.'s motion for a new trial in an early bellwether case, this Court cited extensively to Dr. Rosenzweig's testimony as having provided sufficient support for the plaintiff's claims, in several different areas. *See Huskey v. Ethicon, Inc.*, No. 2:12-CV-05201, 2015 WL 4944339, at **4-8 (S.D.W. Va. Aug. 19, 2015) (discussing Dr. Rosenzweig's testimony that the TVT-O product shrinks and deforms, causing a foreign body reaction; that the heavyweight Prolene mesh was not suitable for implantation in the human body; and that the warnings in the TVT-O IFU about "transient" groin pain were insufficient).

Dr. Rosenzweig is a highly successful pelvic-floor surgeon based in Chicago. He is also an assistant professor of Obstetrics and Gynecology at Rush University Medical Center. Previously, he had fellowships at the State University of New York at Syracuse, and at UCLA. He started a urogynecology program at the University of Illinois-Chicago, and he has performed more than one thousand surgeries in the pelvic floor, including more than 350 surgeries to address complications associated with synthetic mesh products. Dr. Rosenzweig has also published numerous articles and given numerous lectures on the treatments of urinary incontinence and pelvic organ prolapse. (Rule 26 Expert Report of Bruce Rosenzweig, MD as to Standard Midurethral Slings ("Standard Sling Report"), attached as Exhibit A, at pp. 1-2).

This Court has written that "Dr. Rosenzweig has demonstrated extensive knowledge of and experience with the process of polypropylene mesh degradation in the body"; that "[a]lthough Dr. Rosenzweig has never designed vaginal mesh devices, he has considerable familiarity with their structure and use"; and that "Dr. Rosenzweig received thorough training on the implantation of sling products in pelvic repair. *Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at **5-6 (S.D. W. Va. May 5, 2015). As a result, this Court wrote in another case that it "has considered Dr. Rosenzweig as a general causation expert three times in the past, and on each occasion, I have admitted his general causation testimony on the properties of polypropylene mesh." *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 565 (S.D. W. Va. 2014), *as amended* Oct. 29, 2014.

Nonetheless, Coloplast has challenged many of Dr. Rosenzweig's opinions. Several of these challenges ignore this Court's practice, which has been consistent over the years, to address categories of evidence generally, and to leave the specifics for trial, when testimony or other evidence can be evaluated in context. For instance, Plaintiffs are not arguing that the Court

should reverse its prior decisions forbidding testimony on issues such as the Defendant's state of mind or legal conclusions, but Plaintiffs disagree that many of the examples cited by the Defendant fall into those categories. Regardless, this Court should not parse out Dr. Rosenzweig's three expert reports to rule on those issues one-by-one. The court should simply make its usual general rulings and leave the specifics for trial.

There are also two specific issues where the Court should reject Coloplast's arguments in full. Dr. Rosenzweig should be permitted to offer the opinion that Coloplast needed to test its product to determine the effects of the polypropylene mesh on women. Dr. Rosenzweig is not trying to tell Coloplast **how** it should have done its testing, but as an experienced pelvic floor surgeon who has been involved in product testing himself, Dr. Rosenzweig should be able to opine that testing was **necessary**. In addition, there is no merit to the assertion that Dr. Rosenzweig's opinions about non-mesh alternative are unsupported or irrelevant. Dr. Rosenzweig's extensive clinical experience supports his opinions about non-mesh alternatives—which this Court has permitted him to give—and there is no basis to make a blanket determination of relevance as to claims in all 500 states—as evidenced by decisions on remand that have found this exact evidence to be relevant.

The other issues raised by Coloplast present questions that are best raised by cross-examination, rather than by exclusion of his opinions. Dr. Rosenzweig's expertise with regard to pelvic mesh products has been demonstrated time and again, and the same methodology that has led to him giving reliable opinions on numerous products—as sanctioned by this Court on many occasions—is the methodology he used in reaching opinions about Coloplast's products.

For these reasons, Defendant's motion should be denied in its entirety.

ARGUMENT

I. Rule 702/*Daubert* standard

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

The Court is well aware of the application of this standard, but Plaintiffs specifically point to the *Daubert motion* against Dr. Michael Woods for a more complete description of the applicable standards.

II. As to various common issues raised by the Defendant in Section I of its argument, this Court should issue general guidelines and let the trial judge deal with specific issues at trial, as this Court has done in the past.

As the MDLs on the various mesh products have moved into the "Wave" phase, this Court has declined to parse out individual complaints on recurring issues. The first three subsections of Coloplast's brief highlight three of these recurring issues, asserting that Dr.

Rosenzweig should not be permitted to testify as to a) Coloplast's state of mind or corporate conduct; b) narrative descriptions of company documents; and c) legal conclusions. The Court addressed these issues as follows in ruling on the motion as to Dr. Rosenzweig (and many others) in Ethicon Wave 1:

> *First*, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g., In re C. R Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).
>
> *Second*, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4500765, at *7 (S.D. W. Va. Aug. 26, 2016).

There is no reason to depart from that approach here, using general guidance that all counsel, and Dr. Rosenzweig himself, know well by this point. It is not necessary to parse Coloplast's motion point by point. If the Court does so, it will find that many of Coloplast's examples lack merit. For instance, this Court has not forbidden testimony about information available to the manufacturer, for the purpose of discussing what should be in the warnings—a subject on which Dr. Rosenzweig has been consistently permitted to testify. *See, e.g.*, *id.* at *4.

Thus, it is entirely appropriate for Dr. Rosenzweig to discuss Coloplast's knowledge of potential complications with its product. (*See* Def. Br. at 6-7). However, as a counter-example, Dr. Rosenzweig recognizes that he would likely be forbidden to testify as to Coloplast's motives for certain actions, such as increasing sales. (*Id.* at 7).

With regard to Coloplast's internal documents, the Court's order recited above does allow for use of such documents, "for the purpose of explaining the basis for [the expert's] opinions." *In re Ethicon*, 2016 WL 4500765, at *7. That is all Dr. Rosenzweig is doing when he discusses Coloplast's internal documents. This Court has never required that an expert speak directly with the author of an internal document to be qualified to discuss the document at trial, as Coloplast oddly suggests that Dr. Rosenzweig should have done. (*See* Def. Br. at 8). Plaintiffs assume that such a request for Dr. Rosenzweig to speak directly with Coloplast's employees would not have been met warmly. Regardless, Dr. Rosenzweig's use of Coloplast's e-mail is a quintessential issue for the point that the evidence must be evaluated in the context of trial. *See In re Ethicon*, 2016 WL 4500765, at *7; *cf. In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4582233, at *3 (S.D.W. Va. Sept. 1, 2016) (reserving ruling on a relevance issue because it was "best assessed in context during trial").

As to legal conclusions, Dr. Rosenzweig understands not to use certain language at trial, which is all that the Fourth Circuit requires. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("We identify improper legal conclusions by determining whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.") (quotations omitted). Applying that rule in *McIver*, the court allowed testimony that a physician's treatment of certain patients was "illegitimate or inappropriate." *Id.* Again, Coloplast goes too far in saying that Dr. Rosenzweig should be permitted to say that

Coloplast "failed to warn physicians and patients" about certain risks. (Def. Br. at 10). Such words do not have separate and distinct meaning in the law—they employ common language. Conversely, saying that something is "unreasonably dangerous" could be construed as a legal opinion. Again, the Court should state the general rule and leave the rest for objections at trial.

III. This Court should permit Dr. Rosenzweig to opine at least that further testing of Coloplast's products was needed. Dr. Rosenzweig's clinical experience and his experience with testing medical devices sufficiently qualify him.

There is one issue on which Plaintiffs are asking this Court to reconsider a prior decision, and that relates to product testing. Plaintiffs acknowledge that this Court denied Dr. Rosenzweig the opportunity to opine about product testing in *Huskey* and *Edwards*, as recited in the Defendant's brief. (Def. Br. at 10). Notably, Dr. Rosenzweig's challenged testimony does not opine as to **the nature** of the testing that Coloplast needed to perform. In other words, he is not claiming to be an expert on how to design a particular clinical trial. He is simply offering the opinion that "Coloplast should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade … ." (*See* Def. Br. at 11, citing Rosenzweig POP Report at 20, T-Sling Report at 21).

Dr. Rosenzweig's opinions about the inadequacy of Coloplast's testing are the product of his expertise about the oxidizing agents in the female vaginal area. Dr. Rosenzweig's opinion that more testing was needed regarding the effect of polypropylene in the vaginal area is a natural corollary to an opinion Dr. Rosenzweig has been consistently permitted to give—and which is not challenged here—that the mesh degrades *in vivo*. *See, e.g.*, *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *5 (S.D. W. Va. May 5, 2015).

Dr. Rosenzweig is not relying solely on his clinical experience in opining about Ethicon's testing (or lack thereof). Rather, he also has substantial experience with testing genitourinary and pelvic medical devices, including the following:

- Dr. Rosenzweig was involved in the development of an Amnio-infusion catheter, and he helped to develop a randomized controlled trial ("RCT") to test infusion into the uterus, as compared with placing a sham single catheter.
- He worked with EMPI on testing the Innova electrical simulator designed to treat SUI, and he helped to design an RCT to test using a sham similar as compared to an active simulator.
- He was an investigator for a study for Lea Shield and Fem cap, both cervical cap contraceptives. The study was designed to choose the appropriate size to avoid pregnancy while also gaining FDA approval as over-the-counter drugs.

(Rosenzweig Affidavit, attached as Exhibit B, at ¶¶ 4-6).

As to this specific litigation, Dr. Rosenzweig's opinion—which, again, is limited to expressing the need for additional testing—is particularly pertinent, as Coloplast has admitted that it did no testing regarding degradation of polypropylene. Corporate representative Geoffrey A. Daniel testified that Coloplast had done no testing and added: "We rely on literature for the polypropylene performance." (Standard Sling Report, Ex. A, at 22-23). Several articles were being circulated throughout Coloplast addressing the degradation of pelvic mesh products. A Coloplast consultant stated in 2013: "I agree … the companies have not studied the meshes well enough to understand the long term effects. … Mesh degradation is also a real possibility … ." (*Id.* at 23). Another Coloplast consultant forwarded two articles in 2012 that discussed degradation, one of which noted that transvaginal polypropylene mesh has not been extensively

studied and evidence was lacking and showed images of cracks, fissures, peeling and increased roughness of degraded polypropylene mesh." (*Id.* at 23-24). Given that Coloplast's own consultants were sharing these concerns, there is strong support for Dr. Rosenzweig's opinion that additional testing was necessary.

Based on his clinical experience, his experience with product testing, and the knowledge that Dr. Rosenzweig gained from his review of Coloplast's documents, this Court should conclude that Dr. Rosenzweig is qualified to opine about product testing, and that his opinion has a reliable foundation. Therefore, this Court should reject Coloplast's request to issue a blanket exclusion of all opinions related to testing.

IV. This Court should reject Coloplast's effort to pick off certain opinions in Dr. Rosenzweig's expert reports. All of his opinions are well-supported, particularly when his opinions are considered in the context of all of his research and experience—rather than being considered in isolation, as Coloplast suggests.

The Court should next reject all of Coloplast's arguments that try to paint some of Dr. Rosenzweig's well-researched opinions as unreliable. This section will address each of those opinions in turn.

A. Dr. Rosenzweig is well qualified to opine about the properties of polypropylene mesh and the effect of those properties on women, as this Court has held many times. His opinion that a sheath would have added a layer of protection simply builds on those opinions.

In Dr. Rosenzweig's Aris report as to the Aris, Altis and Supris devices—Coloplast's standard midurethral slings—one of the opinions expressed is that the absence of a protective sheath on the devices increases the risks of erosion, infection, migration, slippage, pain, and encapsulation. (Standard Sling Report, Ex. A, at p. 48). It is important to consider this opinion in the context of Dr. Rosenzweig's larger opinions about these products.

Dr. Rosenzweig's first opinion—which he has given many times, and which is not challenged by Coloplast's motion—is that the sling products at issue are not suitable for their intended purpose because they use heavyweight mesh that is dense and stiff, the mesh degrades over time, the mesh deforms due to contracture/shrinkage, the mesh causes foreign body reactions and fibrotic bridging, the mesh causes infections, and the pores collapse with tension. (Standard Sling Report, Ex. A, at 15 (heading), 15-40 (analysis)). Dr. Rosenzweig further opines that the mesh in Coloplast's sling products is too stiff and is not compatible with the vaginal tissue. (*Id.* at 40 (heading), 40-48)).

The sheath issue builds on those existing problems with the mesh, because the sheath would be one way to protect against the fact that the mesh is too heavy and too stiff. As noted in Dr. Rosenzweig's report, the notes from a 2007 Women's Health Advisory Board meeting indicate a belief that a sheath would decrease infection rates. (*Id.* at 48). At that time, Coloplast was receiving reports of "slippage" and erosions due to the stiffness of the mesh. (*Id.* at 48-49). Certain marketing materials by Coloplast indicated that the "protective sheath" that Coloplast was planning to use "absorbs tensioning load." (*Id.* at 49). Dr. Rosenzweig opines that the failure to incorporate the protective sheath on the Aris, Altis and Supris sling devices contributed to the problems caused by the stiff, small-pore heavy polypropylene that was used in the devices. (*Id.* at 49).

This Court has re-affirmed, numerous times, that Dr. Rosenzweig is suitably qualified and has reliable opinions regarding the properties of various pelvic mesh devices that incorporate polypropylene. *See, e.g.*, *Tyree*, 54 F. Supp. 3d at 565; *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 706–07 (S.D.W. Va. 2014); *In re Ethicon, Inc.*, 2016 WL 4500765, at *4. If Dr. Rosenzweig is qualified to discuss the impact of degradation, fraying, small-pores and other

properties of polypropylene, then he is similarly qualified to add one additional detail, that a sheath would have added to the safety of the devices at issue.

B. Dr. Rosenzweig's report and scientific studies support his opinions that two particular features of the Altis, its small size and its use of four-pronged anchors, provided particular problems for patients.

As with his opinion on the sheath, Dr. Rosenzweig's challenged opinion about Coloplast's mini-sling, the Altis, builds upon his opinion in the prior section of his report on the sling devices. In Section (4) of his Standard Sling Report, Dr. Rosenzweig explains that the Aris device is particularly dangerous because it goes through the obturator space. (Standard Sling Report, Ex. A, at 49 (header), 49-53 (analysis)). For instance, one study found that "the relative risk of reoperation after the transobturator procedure was twofold higher than after the retropubic procedure." (*Id.* at 50).

The Altis, discussed in the challenged opinion in Section (5), also goes through the obturator space. (*Id.* at 53). Thus, the Altis is dangerous for the reasons discussed in Section (4)—as well as the issues discussed in sections (1)-(3), which apply to all of Coloplast's slings—but also for the additional reasons addressed in Section (5). The heading may not have been artfully written, but the heading and the text make clear that there are two issues specific to the Altis: It is an unusually small sling, and it uses four-pronged anchors. (*See id.* at 53-56).

Dr. Rosenzweig's report indicates that the Altis is dangerous in part because it "uses four prongs in the anchors that are penetrated into the obturator space." (*Id.* at 53-54). The prior section establishes the danger of placing **any sling** into the obturator space. (*See id.* at 52, citing the conclusions from a 2007 urogynecology conference, which held that trans-obturator slings were "uncomfortable in the thigh area and therefor [patients] prefer retropubic slings to

Transobturator"). Thus, it is common sense that placing plastic anchors with four prongs into that same space would create inherent dangers.

In addition to common sense, Dr. Rosenzweig's opinion is supported by scientific literature. As his report notes, the Altis device is very similar to the TVT-Secur device marketed by Ethicon, Inc. (*Id.* at 54). To the extent that they have minor differences, studies have shown higher complication rates with the Altis than the TVT-Secur. (*Id.*). A European study that is on Dr. Rosenzweig's reliance list did a comprehensive comparison of mini-slings with traditional full-sized mid-urethral slings. *See* Fattah, et al., *Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications*, European Urology 60 (2011), pp. 468-80, attached as Exhibit C). The study concluded that "[t]he current evidence shows that [mini-slings] are associated with inferior patient-reported and objective cure rates on short-term follow-up when compared with [standard midurethral slings]. [Mini-slings] are associated with significantly higher reoperation rates for SUI." (*Id.* at 479). One of the problems cited with mini-slings was the "lack of robustness of their anchoring mechanism to the obturator membrane/muscles." (*Id.* at 472). As discussed in Dr. Rosenzweig's report, the size of the mini-slings also poses a problem, as the "mesh is too short." (Standard Sling Report, Ex. A, at 54). In addition, smaller mesh is stiffer—as Coloplast recognized, stating that it was "approximately 3x stiffer." Coloplast further stated that "[s]ignificance of this result is unknown." (*Id.* at 55).

Based on all of these factors, Dr. Rosenzweig has a reliable basis to opine that the Altis sling presents particular problems due to its size and the nature of the anchors.

C. The fact that surgeons had to make a blind passage with a needle while implanting Coloplast's POP kits does represent a design flaw, and as an experienced pelvic floor surgeon, Dr. Rosenzweig is uniquely qualified to address that issue.

Coloplast's next argument relates to Dr. Rosenzweig's short opinion that the Coloplast POP products are dangerously designed because they require a "blind passage" by the surgeon. (*See* Def. Br. at 14). While Coloplast tries to present this issue as not addressing a design flaw, the design of the product directly impacts the manner in which it has to be implanted. Here, the design of the product requires the surgeon to cut channels with needles through a blind passage, where the surgeon cannot see what he or she is cutting. (Rule 26 Expert Report of Bruce Rosenzweig as to POP Devices ("POP Report"), attached as Exhibit D, at p. 43).

As this Court has written, Dr. Rosenzweig's extensive clinical experience with mesh renders him uniquely qualified to opine as to matters involving mesh surgery. *See, e.g.*, *Herrera-Nevarez v. Ethicon, Inc., et al.*, No. 2:12-CV-01294, 2017 WL 401871, at *2 (S.D. W. Va. Jan. 26, 2017) (noting, more than two years ago, that Dr. Rosenzweig had performed more than 1,000 pelvic floor surgeries and more than 300 surgeries associated with synthetic mesh products). He is, therefore, uniquely qualified to understand whether a device's design necessitates a dangerous surgical process, as it relates to mesh devices. (*See* POP Report, Ex. D, at p. 2, noting that Dr. Rosenzweig has now performed more than 350 surgeries related to mesh complications).

The issue being addressed was known to Coloplast. As noted in Dr. Rosenzweig's POP Report, the company was being warned in 2007 that the transobturator approach—which uses a similar blind passage—presented safety concerns, particularly for new surgeons using the device. (*See id.* at 59 n. 103). Yet, Coloplast doubled down on this problem by designing the POP device with the same problem. Dr. Rosenzweig should be permitted to tell juries why this design flaw created safety issues for women implanted with Coloplast's POP kits.

D. Dr. Rosenzweig is extremely well qualified to opine about the safety of non-mesh procedures, as compared with the safety of mesh implants, as he has done many times in the past. In addition, such evidence is relevant to certain issues, as other courts have recognized, and this Court should not issue a blanket ruling as to relevance in every case, under the laws of all 50 states.

Finally, there is no merit to Coloplast's assertion that Dr. Rosenzweig should be prevented from giving the opinion—which he has offered many times—that traditional mesh surgeries are safer than surgeries using mesh. As far back as the first TVT bellwether trial, this Court permitted Dr. Rosenzweig to discuss the safety comparison between the Burch procedure, which is his preferred surgical method of treating SUI, and Ethicon's TVT device. (*See Lewis v. Ethicon, Inc.*, Day 2 Trial Tr., attached as Exhibit E, at pp. 65-66).

The Court should first reject Coloplast's argument that there is no support for Dr. Rosenzweig's opinion about safety. Dr. Rosenzweig is a pelvic floor surgeon who has decades of experience performing the Burch Culposuspension procedure to treat SUI. As noted, he also has performed more than 350 surgeries involving pelvic mesh products. (Standard Sling Report, Ex. A, at p. 2). His expert reports go into great detail about the various complications associated with Coloplast's standard mesh slings, including but not limited to vaginal extrusion, erosion, dyspareunia, sling migration, infection, pain, hematoma, scarring, transient or permanent urinary retention/obstruction, urethral obstruction, voiding dysfunction, nerve injury, vascular injury, and bladder, bowel, urethra, vessel, and/or nerve perforation. (*Id.* at 63). There are also large lists of complications associated with Coloplast's POP kits and T-Slings. (*See* POP Report, Ex. D, at 48-49; Rule 26 Expert Report of Bruce Rosenzweig as to T-Slings ("T-Sling Report"), attached as Exhibit F, at pp. 45-47). Those opinions are unchallenged, so it would make no sense to hold that Dr. Rosenzweig was unable to compare all of that risk information with the risks that he sees in his own practice, using non-mesh surgical techniques.

Coloplast argues about the lack of clinical trials comparing native tissue repairs with mesh repairs, but those are precisely the type of studies that the medical device companies should have undertaken before placing these dangerous products on the market. Dr. Rosenzweig has analyzed the studies that do exist as to synthetic mesh products, and he cites several of them in his reports. (*See, e.g.*, Standard Sling Report, Ex. A, at p. 87, citing Tamussino, 2001 and 2007; Kuuva 2002; Collinet 2008; Dykorn 2010; Lose 2017; Abbott 2014; and Brown 2017). As Dr. Rosenzweig explains, those studies were not clinical trials to determine safety; they were merely short-term studies designed to determine efficacy. (*Id.* at 86-87). Coloplast's internal e-mails, cited throughout Dr. Rosenzweig's three reports, paint a very different picture of the safety profile of the devices at issue. (*See id.* at 87).[1] Based on his extensive review of the scientific literature regarding mesh products, Coloplast's safety information as described in internal documents, and results from his own practice, Dr. Rosenzweig is exceptionally well qualified to offer a reliable opinion about the differences in complications between non-mesh procedures and the devices at issue.

Meanwhile, this Court should also reject Coloplast's effort to deem Dr. Rosenzweig's opinions irrelevant under the laws of all 50 states, through this general causation motion. This Court has previously expressed an appropriate reluctance to make sweeping generalizations about relevance in response to general motions. For instance, in Ethicon Wave 1, this Court noted that Ethicon had not challenged Dr. Rosenzweig's qualifications to opine that alternative procedures were safer than Ethicon's mesh products, and that it did not challenge the reliability

[1] Plaintiffs note that certain portions of the exhibits, including the Rule 26 report itself, have been redacted at the insistence of Coloplast. Plaintiffs made concessions regarding the scope and propriety of the redactions in order to be able to timely file their response in opposition. However, Plaintiffs expressly reserve their right to challenge the confidential nature of these exhibits. Plaintiffs have already begun the meet and confer process, and intend to file a motion challenging the overbroad confidentiality designations of Coloplast in the coming weeks.

of such opinions. *In re Ethicon, Inc.*, 2016 WL 4500765, at *3. Ethicon did challenge the relevance of such opinions, but this Court declined to wade into that issue, stating that "[t]he relevance of this expert testimony is better decided on a case-by-case basis." *Id.*

When this Court previously held that alternative procedures could not be used to fulfill a safer alternative design requirement under the law of West Virginia, this Court was making a highly specific determination. In the *Mullins* case cited by Coloplast, (*see* Def. Br. at 16-17), this Court was addressing whether alternative procedures could qualify as safer alternative designs, to meet a threshold requirement of West Virginia law. *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942–43 (S.D. W. Va. 2017). The Court's negative answer to that specific question does not dictate the relevance or Dr. Rosenzweig's testimony to all aspects of all claims, under the laws of all 50 states.

For instance, at least two district judges have held, after remand from this Court, that testimony about alternative procedures was relevant to design defect and other issues. In *Wiltgen v. Ethicon, Inc.*, No. 12-CV-2400, 2017 WL 4467455 (N.D. Ill. Oct. 6, 2017), Ethicon argued that the court "should preclude Dr. [Daniel] Elliott from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI." *Id.* at *3. The plaintiffs in *Wiltgen* argued that the alternative procedures advocated by Dr. Elliott were relevant to the risk-utility test for determining a design defect under Illinois law, and that they were relevant to negligence, in determining whether Ethicon had acted as a reasonable manufacturer. *Id.* Plaintiffs also argued that Ethicon was likely to open the door by claiming that its products were the best option for treatment of SUI. *Id.* While the court agreed with this Court's decision as to safer alternative design, it agreed with the plaintiffs that the evidence of alternative procedures was admissible for other purposes, under Illinois law. *Id.* at *4-5. A different judge of the

Northern District of Illinois reached the same conclusion in *Herrera-Nevarez by Springer v. Ethicon, Inc.*, No. 12 C 2404, 2017 WL 3381718 (N.D. Ill. Aug. 6, 2017). The court held that "the availability of other safe and effective procedures to treat the same condition is relevant and admissible, as plaintiffs contend, to show the utility of the defendants' product (factor 1)—a point not addressed in the other cases upon which defendants rely." *Id.* at *7.

Regardless of how this Court feels about those specific decisions, this Court should decline to preclude all federal judges from making that relevance determination after remand. This Court made the right decision in Ethicon Wave 1, when this same issue arose, and this Court should again conclude that "[t]he relevance of this expert testimony is better decided on a case-by-case basis." *In re Ethicon, Inc.*, 2016 WL 4500765, at *3.

CONCLUSION

For all of these reasons, this Court should deny Defendant Coloplast Corp.'s Motion to Exclude or Limit Certain Opinions and Testimony of Bruce Rosenzweig, M.D.,

Respectfully submitted,

/s/Thomas P. Cartmell

Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
tcartmell@wcllp.com
jkuntz@wcllp.com
Telephone: (816) 701-1102

Riley L. Burnett, Jr.
BURNETT LAW FIRM
3737 Buffalo Speedway, 18th Floor
Houston, Texas 77089
RBurnett@rburnettlaw.com
Telephone: (832) 413-4410

Robert Salim
SALIM-BEASLEY, LLC
1901 Texas St.
Natchitoches, LA
robertsalim@cp-tel.net
Telephone: (318) 352-5999

Mark Mueller
MUELLER LAW PLLC
404 W 7th St.
Austin, TX 78701
mark@muellerlaw.com
Telephone: (512) 478-1236

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on May 28, 2019, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Karen H. Beyea-Schroeder
Attorney for Plaintiffs

INDEX OF EXHIBITS

Exhibit A: Rule 26 Expert Report of Bruce Rosenzweig, MD as to Standard Midurethral Slings, excerpts

Exhibit B: Bruce Rosenzweig Affidavit, executed May 9, 2016

Exhibit C: Fattah, et al., *Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications*, European Urology 60 (2011), pp. 468-80

Exhibit D: Rule 26 Expert Report of Bruce Rosenzweig as to POP Devices, excerpts

Exhibit E: *Lewis v. Ethicon, Inc.*, Day 2 Trial Tr., excepts

Exhibit F: Rule 26 Expert Report of Bruce Rosenzweig as to T-Slings, excerpts